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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

SMITH, ZANDRA V

ART UNIT PAPER NUMBER

2877

DATE MAILED: 10/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,874

Applicant(s)

DOUGLAS ET AL.

Examiner

Zandra V. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed July 8, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. A copy of WO 98/19159 was not included in the IDS, accordingly the reference has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by *Grant et al.* (EP 573598).

As to **claim 8**, Grant discloses a test strip holding and reading meter, comprising:
an electronic printed circuit board having alignment fixturing;
an optics system for alignment with the removable test strip, the optics system comprising an emitter, prisms, lenses (col. 10, lines 25-30), and a detector and mounted on the printed circuit board (col. 9, lines 32-50);
a housing (col. 7, lines 10-15);
an optics block holder mounted in the printed circuit board for aligning the test strip and positioning the optics system to focus light (col. 9, lines 32-50); and

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a processor controlling the assay system in accordance with calibration information specific to a reagent associated with the test strip (col. 18, lines 45-58).

As to **claim 14**, Grant discloses everything claimed, as applied above, in addition the set of one or more test strips includes at least two test strips (col. 15, lines 40-42 and col. 17, lines 3-5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Grant et al.* (EP 573598) in view of *DeSimone et al.* (4,833,088).

As to **claim 9**, Grant discloses everything claimed, as applied above, with the exception of a removable calibration chip, however to do so is well known as taught by DeSimone. In the same field of endeavor DeSimone discloses a reagent strip handling mechanism that includes a calibration chip mounted on the reagent strip and removable for cleaning (col. 11, lines 12-21). It would have been obvious to one having ordinary skill in the art at the time of invention to include a removable calibration chip to allow for cleaning of the chip.

As to **claim 15**, Grant and DeSimone disclose everything claimed, as applied above, in addition the set of one or more test strips includes at least two test strips (col. 15, lines 40-42 and col. 17, lines 3-5).

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Claims 10, 12-13, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Grant et al. (EP 573598)* in view of *McAleer et al. (5,989,917)*.

As to **claim 10**, Grant discloses a test strip holding and reading meter, comprising:

an electronic printed circuit board having alignment fixturing:

an optics system for alignment with the removable test strip, the optics system comprising an emitter, prisms, lenses (col. 10, lines 25-30), and a detector and mounted on the printed circuit board (col. 9, lines 32-50);

a housing (col. 7, lines 10-15);

an optics block holder mounted in the printed circuit board for aligning the test strip and positioning the optics system to focus light (col. 9, lines 32-50); and

a processor (col. 18, lines 45-58).

Grant differs from the claimed invention in that the processor does not control the system such that a predetermined number of test strips are tested, however to do so is well known as taught by McAleer. In the same field of endeavor McAleer discloses a glucose monitor and test strip container that includes a processor to control the system such that a predetermined number of test strips are tested (col. 3, lines 49-64). It would have been obvious to one having ordinary skill in the art at the time of invention to include a processor to control the system such that a predetermined number of test strips are tested to maintain proper and accurate testing of the test strip.

As to **claim 12**, Grant discloses a test strip holding and reading meter, comprising:

an electronic printed circuit board having alignment fixturing:

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an optics system for alignment with the removable test strip, the optics system comprising an emitter, prisms, lenses (col. 10, lines 25-30), and a detector and mounted on the printed circuit board (col. 9, lines 32-50);

a housing (col. 7, lines 10-15); and

an optics block holder mounted in the printed circuit board for aligning the test strip and positioning the optics system to focus light (col. 9, lines 32-50).

Grant fails to specifically provide the processor controlling the assay system such that the test strips are assays up to a predetermined expiration date, however to do so is well known as taught by McAleer. In the same field of endeavor McAleer discloses a glucose monitor and test strip container that includes a microprocessor controlling the system such that the test strips are assays up to a predetermined expiration date (col. 4, lines 22-35). It would have been obvious to one having ordinary skill in the art at the time of invention to include a processor controlling the assay system such that the test strips are assays up to a predetermined expiration date to avoid false readings.

As to **claims 13 and 19**, the system of Grant and McAleer discloses everything claimed, as applied above, in addition the predetermined expiration date corresponds to a set of one, two, or more test strips (McAleer, col. 4, lines 22-35).

As to **claim 16**, the system of Grant and McAleer discloses everything claimed, as applied above, in addition the set of one or more test strips includes at least two test strips (col. 15, lines 40-42 and col. 17, lines 3-5).

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Claims 11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Grant et al. (EP 573598)* and *McAleer et al. (5,989,917)* and further in view of *DeSimone et al. (4,833,088)*.

As to **claim 11**, Grant and McAleer disclose everything claimed, as applied above, with the exception of a removable calibration chip, however to do so is well known as taught by DeSimone. In the same field of endeavor DeSimone discloses a reagent strip handling mechanism that includes a calibration chip mounted on the reagent strip and removable for cleaning (col. 11, lines 12-21). It would have been obvious to one having ordinary skill in the art at the time of invention to include a removable calibration chip to allow for cleaning of the chip.

As to **claim 17**, the system of Grant and McAleer discloses everything claimed, as applied above, in addition the set of one or more test strips includes at least two test strips (col. 15, lines 40-42 and col. 17, lines 3-5).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Grant et al. (EP 573598)* and *McAleer et al. (5,989,917)* and further in view of *Poto et al. (5,795,543)*.

As to **claim 18**, the system of Grant and McAleer discloses everything claimed, as applied above, with the exception of the predetermined expiration date corresponding to the housing, however to do so is well known as taught by Poto. In the same field of endeavor Poto discloses a disposable electronic diagnostic instrument that includes an expiration date corresponding to the housing (col. 2, lines 15-34). It would have been obvious to one having ordinary skill in the art at the time of invention to include an expiration date that corresponds to the housing to avoid the necessity of recalibration or cleaning of the instrument.

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Response to Arguments

Applicant's arguments with respect to claims 8-13 have been considered but are moot in view of the new ground(s) of rejection.

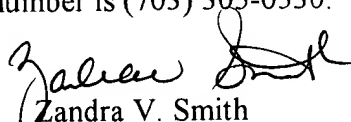
Fax/Telephone Information

Please note that upon further reading it was discovered that Grant discloses lenses in the system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zandra V. Smith whose telephone number is (703) 305-7776. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank G. Font can be reached on (703)308-4881. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0530.


Zandra V. Smith
Examiner
Art Unit 2877

October 7, 2002